NOT FOR PUBLICATON

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES, INC., Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. 3:18-cv-02213-FLW-TJB **OPINION**

WOLFSON, Chief Judge:

This matter arises out of a patent dispute. Sun Pharma Global Fze and Sun Pharmaceutical Industries, Inc. ("Plaintiffs"), have filed an infringement suit, *see* 35 U.S.C. § 271, *et seq*., to protect the market for their drug BromSite after Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Defendants"), sought approval to sell a bio-equivalent generic version. Before the Court are three pretrial motions: Plaintiffs' Motion to Strike the expert report of James T. Carmichael, *see* ECF No. 121, Defendants' Cross-Motion to Preclude "any evidence at trial regarding prior art searches conducted by the [Patent & Trademark Office]," *see* ECF No. 129, and Defendant's Motion to Exclude certain opinions of Dr. Orest Olejnik. *See* ECF No. 165. For the following reasons, Plaintiffs' Motion to Strike is **GRANTED**, Defendants' Cross-Motion to Preclude is **GRANTED in part**, and Defendants' Motion to Exclude is **DENIED in part**.

I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Plaintiffs manufacture BromSite, a patented drug used to treat and prevent ocular pain associated with cataract surgery. *See* U.S. Patent No. 8,778,999; Compl., Ex. A. Defendants,

seeking to launch a bio-equivalent generic version, filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") before Plaintiffs' patent expired. Plaintiffs sued Defendants for infringement, claiming that Defendants' generic contains a chemically identical bromfenac ophthalmic solution in the same proportion, 0.075%, with the same viscosity. *See* Compl., at 2, 7-8. In defense, Defendants (1) assert that their generic has a different viscosity, (2) challenge the validity of the BromSite patent on the grounds that it is anticipated and obvious, and (3) claim that Dr. Lyle Bowman, who helped prosecute BromSite, committed inequitable conduct by failing to submit certain prior art he invented ("Bowman I") to the Patent & Trademark Office ("PTO"). *See* Answer, at 10-11; ECF No. 165, at 2-3.

The parties attempted to settle in 2020, *see* ECF No. 145, but were unable to do so. *See* ECF No. 155. This matter is now scheduled for trial beginning on March 22, 2021. *See* ECF Nos. 179-80. To that end, both parties have submitted pretrial motions to exclude or preclude expert testimony and reports. *See* ECF Nos. 121, 129, 165. On October 25, 2019, Plaintiffs moved to strike James T. Carmichael's Report. They contend that Carmichael offers improper opinion evidence on substantive patent law, *see* ECF No. 121, at 11-12, defects, errors, and omissions in the patent application process, *id.* at 6-8, the motivations of the patent examiner, *id.* at 8-9, whether the patent examiner reviewed Bowman I, *id.* at 10, and the examiner's mental state during patent prosecution. *Id.* at 10-11. Plaintiffs contend that Carmichael's Report should be stricken in its entirety because, absent the above-referenced evidence, it contains nothing more than "undisclosed third party statistical studies" and "rote recitation of facts that are readily obtainable from the [] patent file history," "not in dispute," and "not helpful within the meaning of [Fed. R. Evid.] 702." *Id.* at 13.

On November 18, 2019, Defendants filed a cross-motion to preclude all testimony on the PTO examiner's search history. Defendants insist that Plaintiffs "injected" this issue into the case by submitting that "the [PTO] examiner likely reviewed Bowman I regardless of whether [Plaintiffs] disclosed or did not disclose [it]," and that it would be unfair to exclude the Carmichael Report, which merely responds to that submission. *See* ECF no. 129, at 4. In any event, they argue, any testimony as to the PTO examiner's search history is inadmissible. *Id.* at 7-10.

Finally, on January 8, 2021, Defendants filed a motion to exclude certain expert testimony by Dr. Olejnik. *See* ECF No. 165. Defendants seek to exclude Dr. Olejnik's opinions on "'gelation' of ophthalmic compositions," *id.* at 5-9, whether prior art "anticipated" Plaintiffs' patent, *id.* at 13-16, and whether Plaintiffs' patent is "obvious" in light of prior art, *id.* at 14-19, on the grounds that Dr. Olejnik is unqualified and unreliable.

II. LEGAL STANDARD

Fed. R. Evid. 602 provides that a witness may testify to facts as long as they are within the witness' personal knowledge. *Id.* Fed. R. Evid. 701 provides that a lay witness may offer opinion testimony if it is rationally based on the witness' perception, helpful, and does not require specialized knowledge. *Id.* Fed. R. Evid. 702 provides that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." *Id.*; *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589-92 (1993) (explaining these requirements); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 160-52 (1999) (describing district

courts' "gatekeeping obligation" with respect to expert testimony). In short, the Third Circuit has interpreted Rule 702 to impose a "trilogy of restrictions on expert testimony: qualification, reliability and fit." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003).

III. DISCUSSION

A. Plaintiffs' Motion to Strike the Carmichael Report

Mr. Carmichael is a former examiner in the PTO with no special training in pharmaceuticals, who did not work there at any time relevant to this litigation. *See* Green Decl., Ex. A, ¶ 7. Defendants have offered his Report—which touches on policies, procedures, defects, pressures, and incentives at the PTO—to rebut Plaintiffs' contention that the PTO examiner here "likely reviewed Bowman I regardless of whether [Plaintiffs] disclosed or did not disclose [it]." *Id.*, Ex. D, at 101. Plaintiffs now "agree[] that such a statement if given in testimony may verge on speculative opinion testimony." Pl. Rep. Br., at 5-6. Similar testimony has been found inadmissible before. *See, e.g.*, *Comcast Cable Commc'ns, LLC v. Sprint Commc'ns Co.*, 203 F. Supp. 3d 499, 547 (E.D. Pa. 2016) ("[The expert] provides no basis for his opinion that the examiner must have considered [prior art] references other than generic PTO rules that require a thorough search of the prior art. Expert testimony about the subjective knowledge or state of mind of the examiner is not admissible in the absence of any support in the record.").

Plaintiffs have therefore withdrawn this portion of their argument, Pl. Rep. Br., at 6, and are no longer "attempting to proffer *opinion* testimony from *any witness* speculating as to what the [PTO] examiner personally considered, reviewed, thought, or believed," nor opinion testimony on the examiner's "search history" generally. *Id.* at 10 (emphasis added). Because the Carmichael Report "responds directly to an improper argument [Plaintiffs] injected into this case," Def. Br., at 2 (emphasis removed), and Plaintiffs have affirmatively represented to this Court that they will no

longer elicit opinion testimony on the PTO examiner's search history or infer from that history that the examiner likely reviewed Bowman I or other prior art, I **GRANT** Plaintiffs' Motion to Strike the Carmichael Report in its entirety.[1] *See* Def. Br., at 2 (stating that Defendants have "repeatedly offered to withdraw the Carmichael Report if [Plaintiffs] will withdraw [their] [] argument regarding the Examiner's search"); *id.* at 5 (describing Defendants' offer on September 20, 2019, to "withdraw Mr. Carmichael's . . . report . . . if [Plaintiffs] stipulate[] in writing that [they] will not raise [the argument at issue here] (or any other speculative argument about the Examiner's actions or views about [Bowman I])").[2]

B. Defendants' Cross-Motion to Preclude All Testimony on Search History

In their Cross-Motion, Defendants seek to preclude Plaintiffs from presenting not just opinion but fact testimony on the PTO examiner's search history.[3] *See, e.g.*, Def. Br., at 2, 7

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1 I strike the Report in its entirety because, to the extent that it also contains factual information, such as the history of the BromSite patent, a summary of Federal Register regulations and other law, and a discussion of articles on the patent examination process generally, none of which Plaintiffs dispute, *see* Pl. Br., at 13, it is not helpful under Fed. R. Evid. 702. *See Kuhar v. Petzl Co.*, No. 16-0395, 2018 WL 6331682, at *3 (D.N.J. Dec. 4, 2018) (holding that expert testimony "does not 'fit' the case" when "it merely addresses a fact question" and the facts "are apparently not in dispute"); *S.E.C. v. Lipson*, 46 F. Supp. 2d 758, 763 (N.D. Ill. 1998) ("Expert testimony may not be used merely to repeat or summarize what the jury independently has the ability to understand.").

2 Even if the Carmichael Report did not simply respond to Plaintiffs' now-withdrawn testimony, I would still find it inadmissible because it is speculative. Carmichael purports to draw the same type of inference from the PTO examiner's search history which Defendants found objectionable when Plaintiffs attempted to draw it: that the examiner did *not* likely review Bowman I or other prior art.

3 The parties tried to resolve this dispute on their own to no avail. Plaintiffs construed Defendants' initial offer to withdraw the Carmichael Report, *see* ECF No. 107, at 2, as contingent on "avoid[ing] any commentary on the examiner's search, including information available from the face of the docs in the file itself." Waldon Decl., Ex. C. Defendants understood Plaintiffs' response to "reserv[e] the right to have an expert discuss the examiner's search, and potentially comment on the same." *Id.* ¶¶ 11-12. The parties then met and conferred. Plaintiffs still could not accept Defendants' offer because they wished to call a fact witness to testify to the prosecution history, including the fact of the examiner's search. Defendants, in turn, would not withdraw the Carmichael Report absent an assurance that Plaintiffs "will abstain from proffering [any] testimony on the Examiner's search." *Id.* ¶¶ 15-18. Plaintiffs, finally, proposed withdrawing their contention that "the examiner likely reviewed Bowman I regardless of whether [Plaintiffs] disclosed or did not disclose [it]," if Defendants withdrew the Carmichael Report. *See* Fish Decl., Ex. B. Defendants "did not substantively respond to . . . this offer," *id.*, so Plaintiffs "assume[d] [they] will not accept it." *Id.*

(arguing that Plaintiffs should be "precluded from adducing" or "proffering" "purported 'fact' testimony" on this issue). Specifically, Defendants seek to preclude testimony from Dr. Bowman that the PTO examiner conducted a search for "(LYLE) near2 (BOWMAN).INV" in United States and foreign databases before approving Plaintiffs' BromSite patent, initialed that search as "considered," which returned 69 hits in total, and included it in the prosecution file. *See* Pl. Br., at 4; ECF No. 121, Ex. 5 (summarizing examiner's "Search Strategy and Results," and "Search Info. Incl. Classification," as filed with Non-Final Rejection on October 25, 2012). Defendants argue that such testimony "would violate at least Federal Rules of Evidence 402, 403, 602, 701, and 702." Def. Br., at 7-8.

While Fed. R. Evid. 402 (relevance), 403 (prejudice), 701 (lay opinion), and 702 (expert opinion) do not govern the admissibility of Dr. Bowman's testimony here, Rule 602 does, and Dr. Bowman plainly lacks personal knowledge of the examiner's search history. He cannot therefore testify to the manner, substance, or results of the search. To the extent that Plaintiffs seek to admit the *fact* of the search into evidence (*e.g.*, the terms used and the databases searched), and to demonstrate *that* the PTO examiner conducted the query "(LYLE) near2 (BOWMAN).INV," they may rely on the relevant files from the prosecution history. *See* Fed. R. Evid. 902(1) (providing that signed and sealed public documents are self-authenticating); Fed. R. Evid. 803(8) (providing a hearsay exception for records or statements of a public office); 37 C.F.R. § 42.61(b) ("Certification is not necessary as a condition of admissibility when the evidence to be submitted is a record of the [PTO] to which all parties have access."). Indeed, insofar as they seek to introduce these "undisputed facts found on the face of the publicly-available prosecution history for the

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Plaintiffs nevertheless withdrew the contention, admitting that it is speculative, *see supra*, but Defendants still wish to admit the Carmichael Report into evidence and preclude any fact testimony on the examiner's search history. *See supra*.

[BromSite] patent," Pl. Rep. Br., at 6, Dr. Bowman's testimony is not only precluded by Rule 602 but unnecessary.[4]

C. Defendants' Daubert *Motion*

Defendants also move to exclude the opinions of Dr. Olejnik, apparently Plaintiffs' only expert witness, on (1) whether prior art "anticipated" Bromsite, Def. Mot., at 13-16, (2) whether BromSite is "obvious" in light of prior art, *id.* at 14-19, and (3) various issues relating to the "'gelation' of ophthalmic compositions." *Id.* at 5-9. Defendants argue that Dr. Olejnik misstated the law governing anticipation, improperly imported a limitation from the patent specification into the claims in analyzing obviousness, and did not satisfactorily define "gel."

Fed. R. Evid. 702 imposes a "trilogy of restrictions on expert testimony: qualification, reliability and fit." *Calhoun*, 350 F.3d at 321. Qualifications and reliability are relevant here. A

4 This is not to say that Dr. Bowman cannot testify to the effect the PTO examiner's search history had on his mental state at the time of the BromSite prosecution, if indeed he knew about and reviewed it, since that may be relevant to Defendants' inequitable conduct claim—*i.e.*, to whether, in view of the search terms, Dr. Bowman intended to deceive the PTO by not disclosing Bowman I. *See, e.g.*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290-91 (Fed. Cir. 2011) ("To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO . . . . In a case involving nondisclosure of information [as here], clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference. In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.") (internal citations and quotations omitted) (emphasis in original); *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 809 (Fed. Cir. 1990) (explaining that "courts must view the involved conduct 'in light of all the evidence'") (citations omitted); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) (explaining that, to meet the clear and convincing evidence standard, the specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence"); *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 873 (Fed. Cir. 1988) (explaining that the evidence "must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances") (emphasis added); *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (explaining that, when there are multiple reasonable inferences that may be drawn, the court cannot infer intent to deceive). Courts have rejected claims of inequitable conduct before based, in part, on search history. *See, e.g.*, *Cordis Corp. v. Boston Scientific Corp.*, 641 F. Supp. 2d 353, 358-59 (D. Del. 2009) (holding that search history did not give rise to inference of specific intent to deceive, even though applicant had a copy of it but did not read it); *Syngenta Seeds, Inc. v. Monsanto Co.*, 404 F. Supp. 2d 584, 593 (D. Del. 2005) (holding that disclosing search history "show[ed] a lack of intent to deceive").

district court must first qualify an expert witness to testify. To be qualified, the witness must "possess specialized expertise." *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). The Third Circuit has "interpreted this requirement liberally," holding that "a broad range of knowledge, skills, and training qualify an expert as such." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994); *see also SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010) (observing that district courts have "wide latitude" to qualify experts). Although Defendants assert that Dr. Olejnik is not qualified to testify on gels/gelation, anticipation, or obviousness, *see* Def. Mot., at 12, the crux of their motion is that his opinions are unreliable. *See* Def. Mot., at 1. Defendants never really question Dr. Olejnik's pharmaceutical training, experience with ophthalmic formulations, credentials, or whether he has sufficient knowledge to opine on specific issues within his field of expertise such as the ones presented here. *Accord In re Human Tissue Prod. Liab. Litig.*, 582 F. Supp. 2d 644, 655 (D.N.J. 2008) ("[C]ourts have been cautioned not to exclude expert testimony merely because the court feels that the expert is not the best qualified or that the expert does not possess the most appropriate specialization.") (citing *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996)). Although Dr. Olejnik's deposition indicates that he has not previously conducted studies or experiments with BromSite, that alone does not disqualify him. *Id.* I thus analyze the parties' dispute in terms of the reliability.

Expert testimony must "rest[] on a reliable foundation" to be admissible. *Daubert*, 509 U.S. at 597. This means that it "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" *Paoli*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 590). "[T]he reliability analysis applies to all aspects of an expert's testimony," not just the methodology, such as "the facts underlying the expert's opinion, [and] the link between the facts and the conclusion." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999); *see also ZF*

Meritor, LLC v. Eaton Corp., 696 F.3d 254, 290 (3d Cir. 2012). In determining whether an expert opinion is reliable, the Third Circuit has instructed district courts to consider several, non-exhaustive factors:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Calhoun, 350 F.3d at 321 (citations omitted).

Reliability is not, however, equivalent to "correctness." *In re Paoli*, 35 F.3d at 744 (concluding that the "evidentiary requirement of reliability" amounts to a lower burden "than the merits standard of correctness"); *Krys v. Aaron*, 112 F. Supp. 3d 181, 189 (D.N.J. 2015) (same); *Smart Vent, Inc. v. USA Floodair Vents, Ltd.*, 193 F. Supp. 3d 395, 409-10 (D.N.J. 2016) (same). If "an expert's scientific testimony rests upon good grounds . . . it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from [] scrutiny for fear that [the factfinder] will not grasp its complexities or satisfactorily weigh its inadequacies." *United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) (quoting *Ruiz-Troche v. Pepsi Cola Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (further citations omitted)). In other words, the "[t]he evidentiary requirement of reliability is not that high even given the evidentiary gauntlet facing the proponent of expert testimony under Rule 702," *Pineda v. Ford Motor Co.*, 520 F.3d 237, 247 (3d Cir. 2008) (quoting *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir.1999)), and "courts have 'considerable leeway' in determining the reliability of particular expert testimony," *Simmons v. Ford Motor Co.*, 132 Fed. App'x. 950, 952 (3d Cir. 2005) (quoting *Kumho*, 526 U.S. at 152-53), including "*how* to determine reliability" in the first instance. *Kumho*, 526 U.S. at 142.

With this framework in hand, I examine each of Dr. Olejnik's challenged opinions starting with anticipation.

i. Anticipation

Defendants argue that "Dr. Olejnik's expert report and deposition testimony show that he violated [legal] precepts in conducting his anticipation analysis," Def. Mot., at 13, and his opinion on whether prior art anticipated BromSite is inadmissible to that extent.

The law governing anticipation is well-settled. *See Ricoh Corp. v. Pitney Bowes, Inc.*, 513 F. Supp. 2d 96, 98 (D.N.J. 2007). Under 35 U.S.C. § 102(b), a person is entitled to a patent unless the invention was "described in a printed publication in this or a foreign country . . . more than one year prior to the date of application for patent in the United States." *Id.* "[E]ach and every limitation" must be "found either expressly or inherently in a single prior art reference" to invalidate a patent based on anticipation. *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir. 2002). This "requires that the four corners of a single, prior art document describe every element . . . such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys. Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1082 (Fed. Cir. 2008) ("For a reference to anticipate it must enable one of skill in the art to make or use the invention.").

Defendants begin by claiming that Dr. Olejnik's Report misapplies anticipation law because "he did not do an element-by-element comparison of the [BromSite] patent claims to Bowman I." Def. Mot., at 11. Instead, he discussed Bowman I "in its entirety" or "as a whole," *id.* at 14 (quoting Ex. C, ¶¶ 139-40), which "render[s] all of his opinions thoroughly unreliable." *Id.* at 17 (citing cases). Based solely on these arguments, I will not exclude this testimony at this point, without prejudice as to timely objections at trial on other grounds.

First, Dr. Olejnik accurately summarizes anticipation law in his Report, a point Defendants overlook. *See* ECF No. 165, Ex. 4, at ¶ 15 ("I understand that a patent claim is anticipated by a prior art reference if that reference discloses each and every element of the claim, either expressly or inherently. For a claim limitation to be inherently present in the prior art, I understand it must be necessary (i.e., always) present, not possibly or probably present."). Second, *Defendants'* expert must perform an element-by-element analysis, since *they* seek to invalidate the BromSite patent. *See Union Oil Co. of California v. Atl. Richfield Co.*, 208 F.3d 989, 994-95 (Fed. Cir. 2000) ("This Court requires that *a party seeking to invalidate* a patent under § 102 show that the allegedly invalidating prior art contains each and every element of [the] claimed invention.") (emphasis added). As Plaintiffs' expert, who seeks to undercut Defendants' invalidity defense, Dr. Olejnik need only show that Bowman I (or other prior art) did not describe at least one element in BromSite. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991) ("There must be *no* difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.") (emphasis added). In any event, Dr. Olejnik appears to discuss particular elements of prior art, including whether it contains bromfenac, its pH level, its use of sugar, its use of beta blockers, the presence of timolol, and whether it is a gel or viscous substance, *see* ECF No. 165, Ex. 4, ¶¶ 38, 143-47, 151, 153-67, 270, 285, 298, a point Defendants discerned elsewhere in their motion.

At bottom, Defendants' argument is that Dr. Olejnik's opinion on whether prior art anticipates BromSite is "fatally flawed" and "wholly incorrect." Def. Mot., at 15-16. However, rather than attacking the methods Dr. Olejnik uses, Defendants mainly disagree with his conclusions on the science: the prior art does not describe bromfenac, a species of the anti-inflammatory genus, or a pH level "of about 7.4 to 8.5," which is contained within the range

disclosed in that art but is released over time in BromSite, apparently because it is a gel. ECF No. 165, Ex. 4, ¶¶ 143-47, 151. Simply, "[i]t is not the Court's role to settle [such] scientific disputes." *United States v. W.R. Grace*, 455 F. Supp. 2d 1196, 1199 (D. Mont. 2006). The Court must focus "on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. Bottom-line disagreements more appropriately go to the weight of the evidence. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 842 (Fed. Cir. 2010) ("*Daubert* and Rule 702 are safeguards against unreliable and irrelevant opinions, not guarantees of correctness."); *In re Paoli*, 35 F.3d at 744 (distinguishing reliability from "correctness"); *Broe v. Manns*, No. 15-985, 2016 WL 7048988, at *4 (M.D. Pa. Dec. 5, 2016) ("Any disagreement plaintiffs have with the expert can be dealt with through cross examination, [and] presentation of contrary evidence."); *In re Gabapentin Patent Litig.*, No. 00-2931, 2011 WL 12516763, at *10 (D.N.J. Apr. 8, 2011) (concluding that disagreement between experts regarding applying a methodology to the facts, as here, presents a classic "battle of the experts" to be resolved by the factfinder); *see also Phillips v. Cohen*, 400 F.3d 388, 400 (6th Cir. 2005) ("[C]ompeting expert opinions present the 'classic battle of the experts' and it [is] up to a [factfinder] to evaluate what weight and credibility each expert opinion deserves."); *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK, Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003) (noting that, on a *Daubert* motion, "it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence").

Defendants unsuccessfully direct the Court back to Dr. Olejnik's deposition, where he perhaps confused a particular aspect of anticipation law regarding motivation. *See* Def. Mot., at 16-17. Even if true, that is not grounds for excluding his testimony, as long as his Report is accurate on the law. *See, e.g.*, *Huawei*, 2017 WL 4619791, at *3 (denying motion to exclude where deposition testimony incorrectly stated the law but report correctly stated it). And the weight of

Dr. Olejnik's testimony on this issue, like all other issues, will ultimately be judged by me, the factfinder, at trial.

ii. Obviousness

Defendants next argue that Dr. Olejnik's opinion on the obviousness of BromSite are inadmissible because he "improperly based [this opinion] on the premise that the [BromSite] patent claims require a sustained release of bromfenac," even though the claims do not mention any particular drug release profile.[5] Def. Mot., at 18-19. For this reason, Defendants assert, Dr. Olejnik added a limitation where none should exist, and contradicted the "plain and ordinary meaning" of the claim terms. Again, based solely on these arguments, I will not exclude this testimony at this point, without prejudice as to timely objections at trial on other grounds.

"[E]xpert testimony inconsistent with the Court's claim construction is unreliable and unhelpful to the finder of fact," and should be excluded under *Daubert* on that basis. *Personalized User Model, L.L.P. v. Google, Inc.*, No. 09-525, 2014 WL 807736, at *1 (D. Del. Feb. 27, 2014); *see also Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1321 (Fed. Cir. 2009). Expert testimony based on an impermissible claim construction is likewise irrelevant, unhelpful, and confusing. *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 n.2 (Fed. Cir. 2006). However, when a court does not construe a term or orders that ordinary meaning applies, as here, *see* ECF No. 49 (joint claim construction order giving various "indefinite" claim terms their "plain and ordinary meaning"), expert testimony on how a skilled artisan would understand the term is appropriate to assist the factfinder and admissible to that extent, *see EMC*

5 Claim 1 is: "A topical ophthalmic composition formulated for application to the eye, said composition comprising a therapeutically effective amount of bromfenac and a flowable crosslinked carboxy-containing polycarbophil and mucoadhesive polymer, wherein the composition has a viscosity in the range of about 1,000 to about 3,400 cps and a pH of about 7.4 to about 8.5." *See* U.S. Patent No. 8,778,999; Compl., Ex. A.

Corp. v. Pure Storage, Inc., 154 F. Supp. 3d 81, 109-10 (D. Del. 2016); *Avid Tech., Inc. v. Harmonic, Inc.*, No. 11-1040, 2014 WL 7206301, at *4 (D. Del. Dec. 17, 2014); *Cave Consulting Grp., LLC v. OptumInsight, Inc.*, No. 11-469, 2015 WL 740379, at *15 (N.D. Cal. Feb. 20, 2015), as long as the testimony does not itself amount to claim construction. *See Cordis Corp. v. Bos. Scientific Corp.*, 561 F.3d 1319, 1337 (Fed. Cir. 2009); *CytoLogix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1172-73 (Fed. Cir. 2005).

Here, Defendants do not explain which claim term(s) Dr. Olejnik apparently misconstrued. *See* ECF No. 49. They instead excerpt portions of Dr. Olejnik's Report, *see* ECF No. 165, Ex. 4, ¶¶ 164-75, where he rebuts Dr. Hanes' opinion that a person of ordinary skill in the art would have been "highly motivated" to "formulate [] a composition at the claimed polycarbophil concentrations . . . . *while still allowing for prolonged efficacious release of bromfenac over a long period of time*." Wheatley Decl., Ex. C, ¶ 878 (emphasis added). For instance, Dr. Olejnik states that "[a] person of ordinary skill in the art would understand that [certain prior art] . . . would not be released in a sustained manner over time according to the mechanism identified by [that patent]." ECF No. 165, Ex. 4, ¶ 164. He also states that "[n]othing" he has seen "would motivate a person [skilled in the arts] to choose bromfenac to make an extended release." *Id.* ¶ 173. He further opines that "even if one accepts Dr. Hanes' conclusion that a person of skill would have been motivated to put bromfenac in a sustained release formulation containing polycarbophil, [that person] would not have had a reasonable expectation of success that formulating bromfenaic . . . with polycarbophil would achieve sustained release." *Id.* ¶ 174.

Based on these excerpts, Dr. Olejnik appears to confine his opinion to the question whether a skilled artisan would understand the plain and ordinary meaning of the prior art and the claim

terms in BromSite in the manner proposed by Dr. Hanes. *Accord EMC Corp*, 154 F. Supp. 3d at 110 (admitting in part and excluding in part expert testimony in light of a claim construction order).

iii. Gelation

Finally, Defendants assert that Dr. Olejnik cannot testify to any of the following issues regarding gels/gelation: "(i) what the prior art teaches about gelation; (ii) what an ordinarily-skilled artisan would expect regarding gelation; (iii) what said artisan would be motivated to do with regard to gelation; (iv) whether Bowman I is cumulative . . . because [it] purportedly uses a viscous suspension instead of gelation; and (v) whether Dr. Bowman's First and Second Declarations were false and misleading." Def. Mot., at 9. For support, they point to portions of Dr. Olejnik's deposition in which he declined to define gels or viscous suspensions, *id.* at 10, and would not testify—without conducting further research—whether BromSite is a gel or suspension, whether BromSite gels in the bottle or the eye, or whether povidone (an ingredient in certain prior art) gels in water. *Id.* at 9-12. Because Dr. Olejnik could not, or would not, give such testimony in the context of the BromSite patent, Defendants urge that I find his opinions on gel/gelation unreliable.

To begin, gelation is important in this case because BromSite's patent specification states that the composition gels in the eye and Dr. Bowman apparently distinguished BromSite from prior art (partly) on this basis during the prosecution history. *See, e.g.*, ECF No. 165, Ex. 3, Lyle Declr. Indeed, Plaintiffs contend that one of BromSite's essential features is its delivery system: because the composition gels, the cornea is able to absorb more medication over a longer period of time, thereby increasing its pain reduction properties. To that end, the parties' experts disagree sharply on gelation-related issues. Defendants' expert, Dr. Hanes, opines that Dr. Bowman did not accurately describe to the PTO examiner how and when polycarbophils gel, *see* ECF No. 179, at 25-26, and challenges whether gelation actually distinguishes BromSite from prior art. Like Dr.

Bowman, Dr. Olejnik draws a distinction between gels and viscous formulations, opines that BromSite gels whereas prior art does not, and connects BromSite's enhanced efficacy to gelation. *See, e.g.*, ECF No. 165, Ex. 4, ¶¶ 38, 270, 285, 298. Suffice it to say, the concept of gelation is a major point of contention in this case.

Consequently, Dr. Olejnik clearly relies on a particular—albeit unstated—definition of gels/gelation in his Report, and opines rather extensively on prior art on that basis. *See, e.g.*, ECF No. 165, Ex. 4, ¶ 38 (distinguishing gels from viscous formulations in the context of Bowman I); *id.* at ¶ 270 (stating that Bowman I "does not rely on the gelation effect of polycarbophil"); *id.* ¶ 298 (stating that the composition in Bowman I is a "viscous liquid or viscous suspension," as opposed to a gel); *id.* at ¶ 285 (stating that applying a commercial embodiment of Bowman I to the eye "would not likely substantially change viscosity"). Yet, without explanation, Dr. Olejnik does not appear to define a gel or gelation anywhere in his Report, nor do Plaintiffs point to any portion indicating otherwise.

Apart from that omission, Dr. Olejnik either could not or would not define gels/gelation in his deposition in essentially any context. *See, e.g.*, Wheatley Decl., Ex. B, at T42:1-16 (stating "I'd have to go back and research it more" and "I'd have to go back and review the definitions of what these gels are" when questioned in the context of an article proposing a particular definition of a gel); *id.* at T60:10-20 (stating "I'd have to go and look at the definition," "I'd have go research it," and "I'm not prepared to answer [] at this point in time" when questioned in the context of his personal view on gelation); *id.* at 59:9-14 (stating "I would need to re-review the definition of gels" when questioned in the context of the BromSite patent); *id.* at T52:25-53:12 (stating "I'd have to look at that" when questioned whether there is a minimum viscosity before a suspension becomes a gel); *id.* at T53:19-54:2 (stating "I've not looked at BromSite in the bottle" and "I'd have to look

at the product to be able to respond" when questioned whether BromSite gels in the bottle); *id.* at T56:7-18, T55:24-56:6 (stating "I'd have to go back and study it" and "I'm not saying whether it is a gel or a liquid" when questioned whether BromSite gels in the eye); *id.* at T67:21-25 (stating "I'd have to go and do an experiment" when questioned whether the closest prior art, Xibrom, gels in water). Despite all of that, Dr. Olejnik believed that "[t]here's no reason why [he] should not be able to [proffer a definition of a gel at trial]." *Id.* at T58:19-20, T59:19-21. In short, although Dr. Olejnik assumes a particular understanding of gels/gelation in his Report, on the basis of which he opines repeatedly on Bowman I, among other prior art, he does not state that definition in the Report nor proffer a definition in his deposition when asked to do so.

I find this perplexing, and it gives me great pause as to the reliability of (at least) Dr. Olejnik's opinions on gels/gelation. Still, I am not prepared to decide whether to exclude these opinions until I hear testimony on exactly what Dr. Olejnik presumed gels/gelation to mean when he wrote his Report, and defer my *Daubert* determination to trial, at which point I will "apply Rule 702 to assess . . . reliability . . . before weighing [Dr. Olejnik's] opinions to decide [any] triable issue." *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832-33 (3d Cir. 2020) ("[A] district court has leeway [in a bench trial] about whether . . . . [to] conditionally admit the expert testimony subject to a later Rule 702 determination.") (internal citations and quotations omitted); *In re Unisys*, 173 F.3d 145, 155-58 (3d Cir. 1999) ("When the role of the gatekeeper to admit or exclude evidence (the judge) and the role of the factfinder to assess and weigh the evidence . . . (the jury) are one and the same, the judge . . . must be given great deference by this Court[ ] and . . . should not be required to waste judicial time."); *see also Clark v. Richman*, 339 F. Supp. 2d 631, (M.D. Pa. Oct. 7, 2004) ("[T]he court will take plaintiffs' objections to [the expert report] into consideration during the bench trial to best determine the overlapping weight

and admissibility issues contemporaneously, as other courts have done."); *Astra Aktiebolag v. Andrx Pharm., Inc.*, 222 F. Supp. 2d 423, 486 (S.D.N.Y. 2002) (same); *Berry v. School Dist., of City of Benton Harbor,* 195 F. Supp. 2d 971, 977 n.3 (W.D. Mich. 2002) (same); *Ekotek Site PRP Comm. v. Self*, 1 F. Supp. 2d 1282, 1296 n.5 (D. Utah 1998) (same).

Because gelation is perhaps fundamental to the BromSite patent, *see supra*, in making my *Daubert* determination, I will also decide what other aspects of Dr. Olejnik's Report are unreliable, if any, based on his gelation opinions. In other words, I will determine the impact on the remainder of Dr. Olejnik's Report if I find his opinions on gelation inadmissible. Even if admissible, Plaintiffs are well-advised that Dr. Olejnik's testimony on this issue will be subject to limitations. He will not be permitted to go beyond the scope of his Report and deposition, proffer a definition of gels/gelation or any other terms on which he did not rely therein, or otherwise bolster his trial testimony based on research conducted, literature reviewed, or experiments performed after he submitted the Report and was deposed.

IV. CONCLUSION

Plaintiffs' Motion to Strike the Carmichael Report in its entirety is **GRANTED** in light of their concession not to offer any opinion testimony on the PTO examiner's search history or draw any speculative inferences as to what prior art the examiner likely reviewed. Defendants' Cross-Motion to Preclude all testimony on the PTO examiner's search history is **GRANTED in part**, in that Dr. Bowman may not testify merely to the fact of the search history, but may testify to the effect the search history had on his mental state, if he knew about or reviewed it. Defendants' Motion to Exclude certain opinions of Dr. Olejnik is **DENIED in part** with respect to Dr. Olejnik's opinions on anticipation and obviousness, without prejudice as to timely objections at trial stating

other grounds for excluding these opinions, but I defer my determination on the reliability of Dr. Olejnik's opinions on gels/gelation to trial.

DATED: March 8, 2021

/s/ Freda L. Wolfson
U.S. Chief District Judge